1. **(Previously presented)** A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:

introducing into the cell a first nucleic acid molecule comprising the *tet* operator-linked gene;

introducing into the cell a second nucleic acid molecule encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells;

wherein the first and second nucleic acid molecules are not covalently linked to each other; and

modulating the concentration of a tetracycline, or analogue thereof, in the subject.

18. **(Previously presented)** A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:

introducing into the cell a single nucleic acid molecule comprising the *tet* operator-linked gene and also encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells; and

modulating the concentration of a tetracycline, or analogue thereof, in the subject.

2. **(Previously presented)** The method of claim 1 or 18, wherein the Tet repressor of the tTA is a Tn10-derived Tet repressor.

3. **(Previously presented)** The method of claim 1 or 18, wherein the polypeptide of the tTA which directly or indirectly activates transcription in eucaryotic cells is from herpes simplex virus virion protein 16.

4. **(Previously presented)** The method of claim 18, wherein the nucleic acid molecule encoding the tTA is integrated randomly in a chromosome of the cell.

5. **(Previously presented)** The method of claim 18, wherein the nucleic acid molecule encoding the tTA is integrated at a predetermined location within a chromosome of the cell.

6. **(Previously presented)** The method of claim 1 or 18, wherein the nucleic acid molecule encoding the tTA is introduced into the cell *ex vivo*, the method further comprising administering the cell to the subject.

Claims 7-8. **(Canceled)**

9. **(Previously presented)** The method of claim 1 or 18, wherein the tetracycline analogue is anhydrotetracycline, doxycycline or cyanotetracycline.

10. **(Previously presented)** A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:

obtaining the cell from the subject;

introducing into the cell a first nucleic acid molecule comprising the *tet* operator-linked gene;

introducing into the cell a second nucleic acid molecule encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells, to form a modified cell;

wherein the first and second nucleic acid molecules are not covalently linked to each other;

administering the modified cell to the subject; and

modulating the concentration of a tetracycline, or analogue thereof, in the subject.

19. **(Previously presented)** A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:

obtaining the cell from the subject;

introducing into the cell a single nucleic acid molecule comprising the *tet* operator-linked gene and also encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells, to form a modified cell;

administering the modified cell to the subject; and

modulating the concentration of a tetracycline, or analogue thereof, in the subject.

11. **(Previously presented)** The method of claim 10 or 19, wherein the Tet repressor of the tTA is a Tn10-derived Tet repressor.

12. **(Previously presented)** The method of claim 10 or 19, wherein the polypeptide of the tTA which directly or indirectly activates transcription in eucaryotic cells is from herpes simplex virus virion protein 16.

13. **(Previously presented)** The method of claim 10 or 19, wherein the nucleic acid molecule encoding the tTA is integrated randomly in a chromosome of the cell.

14. **(Previously presented)** The method of claim 10 or 19, wherein the nucleic acid molecule encoding the tTA is integrated by homologous recombination at a predetermined location within a chromosome of the cell.

Claims 15-16. **(Canceled)**

17. **(Previously presented)** The method of claim 10 or 19, wherein the tetracycline analogue is anhydrotetracycline, doxycycline or cyanotetracycline.